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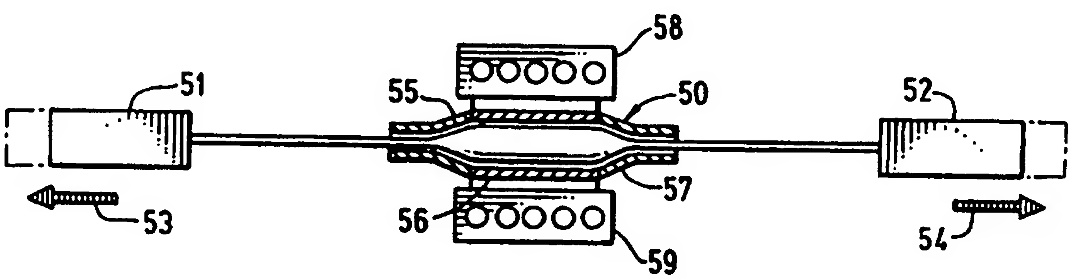

(57) Abstract

A high strength, relatively inelastic balloon having a well defined shape and a high degree of clarity which is particularly suitable for dilatation catheters used in angioplasty procedures. The method of making the balloon includes primary blowing a preform of the desired composition with high levels of radial and axial stretching which provide a blow-up ratio greater than 32, followed by a secondary blowing of the primary blown balloon at a temperature of about 140° and about 160 °C in a mold having dimension of at least 1 % greater in all directions than the dimensions of the primary balloon mold. The secondary blowing minimizes translucence and allows development of balloon shape and dimensions which accurately replicate the interior chamber of the mold.

HIGH STRENGTH DILATATION BALLOONS

BACKGROUND OF THE INVENTION

This invention is generally directed to inelastic balloons and a method for making such balloons and particularly to inelastic dilatation balloons used in peripheral and coronary angioplasty procedures.

Coronary angioplasty procedures typically involve introducing a balloon dilatation catheter into the patient's peripheral arterial system and advancing the catheter through the patient's aorta and into the coronary arteries thereof until the balloon on the catheter extends across the stenosis to be dilated. The balloon is then inflated one or more time to dilate the stenosis and thereby increase blood flow through the coronary artery. The angioplasty procedures for peripheral arteries are very similar to coronary procedures except they are performed in peripheral arteries rather than coronary arteries.

The balloons on dilatation catheters are generally formed of relatively inelastic polymeric materials, so that when they are inflated within a stenotic region of a patient's artery they will not expand much

beyond the native diameter of the healthy artery adjacent the stenotic region. Inelastic polymeric materials which have been use to make dilatation balloons include polyvinyl chloride, polyethylene, poly(ethylene) terephthalate (PET), nylon, and polyolefins such as Surlyn® which is available from E. I. Dupont de Nemcurs and Co., Wilmington, Delaware.

While PET intrinsically has relatively high strength and low compliance, its actual final properties are process dependent. For example, the stretch ratios in the hoop and axial directions which are developed when a PET balloon is blown from a parison or preform have significant effects on the tensile strength of a PET balloon, with larger stretch ratios providing greater tensile strengths. Unfortunately, however, as the stretch ratios (and thus tensile strengths) increase to very high levels, the PET balloons tend to develop a semi-translucence, referred to as "pearlescence", which is apparently due to very fine micro-fracturing of the inside surface of the balloon. The resultant loss in clarity is found to be unacceptable in many applications of PET as well as other high strength polymeric materials.

While many of the above polymeric materials have been widely used in dilatation catheters for both coronary and peripheral artery use, there is a continual need to improve the properties of polymeric balloons for intravascular uses. It is of particular interest to increase the tensile strength of such materials in order to allow for a thinner balloon wall which in turn reduces the profile of the balloon. However,

improvement in tensile strength should not be at the expense of other properties, e.g. clarity, as discussed above. The present invention provides an improved product and a method for making an improved product without the loss of desireable properties.

SUMMARY OF THE INVENTION

The present invention is directed to a high strength relatively inelastic balloon and to an improved method for making the balloon.

In one embodiment of the invention an inelastic balloon is formed by heating a portion of a tubular preform or parison of high strength thermoplastic polymeric material to a temperature within the visco-elastic range of the polymeric material and expanding the heated portion of the preform to the desired dimensions by introducing fluid at relatively high pressure into the interior of the preform and then cooling the preform after the expansion. The blow-up ratio, which is the product of the ratio of stretch in the hoop direction based on the inside diameter (commonly called the hoop-stretch ratio), and the ratio of stretch in the axial direction (commonly called the axial-stretch ratio), generally should be in excess of about 27 and preferably above about 34 to provide a very high degree of orientation in the final product. The minimum stretch in the hoop direction is above about 6:1, preferably above about 7.4:1 and in the axial direction is above about 4:1, preferably above about 4.6:1.

Semi-translucence formed by blowing the preform with such high blow-up ratios described above can be minimized or eliminated by expanding the primary blown balloon at a temperature of about 140° to about 160° C. within a mold having an interior which is larger than the inflated exterior of the primary blown balloon in all directions by about 1% to about 5%. Fluid pressures of about 1 to about 5 atmospheres for about 0.25 to about 5 minutes are usually adequate to expand the balloon sufficiently to completely fill the interior of the secondary mold and to accurately replicate the shape and dimensions thereof. This treatment greatly reduces the pearlescence and therefore increases the clarity of the balloon and provides a greater degree of thermal and shape stability to the balloon. For example, there is little tendency for the secondary blown balloon to shrink when it is exposed to moderate temperatures which are found in conventional sterilization procedures.

In another aspect of the invention it has been found that radiation heating of the preform prior to expansion to form the primary balloon provides a more uniform heating of the wall of the preform which when expanded forms a balloon which has more uniform wall properties such as tensile strength and expansion.

Another aspect of the invention is directed to an improved method for preparing the preform wherein the portions of the preform which are adjacent to the portion which forms the working portion of the balloon are treated with radiation in the IR region, e.g a wavelength of

about 5 to about 10 microns. Tension is applied to the thus heated preform so as to preferentially extend the portions heated by IR irradiation. The application of tension to the preform may by varied so as to form tapers in the region of the preform immediately adjacent both sides of the unheated portion of the preform which is subsequently expanded to form the balloon.

The final balloon after secondary blowing is clear, is relatively inelastic and has a tensile strength of above about 50 ksi, usually above about 70 ksi. It also exhibits a limited radial expansion of about 0.0005 inch/atmosphere to about 0.003 inch/atmosphere at an internal pressure of about 150 psi. The secondary blown balloon accurately replicates the size and shape of the interior of the secondary mold so as to provide greatly improved quality.

These and other advantages of the invention will become apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of a tubular member and a preform formed out of the tubular member.

Fig. 2 is a schematic top view of the assembly for forming the tubular member into the preform.

Fig. 3 is a schematic elevational view, partially in section, of the assembly shown in Fig. 2 taken along the line 3-3.

Fig. 4 is a schematic illustration of a preform and a balloon after primary blowing.

Fig. 5 is a schematic elevational view, partially is section, of an assembly for the primary blowing of a preform into a balloon.

Fig. 6 is a schematic plan view of the assembly shown in Fig. 5 taken along the lines 5-5.

Fig. 7 is an enlarged elevational view, partially in section, of the mold and balloon after the primary blowing of the balloon.

Fig. 8 is a schematic illustration of a cloudy primary blown balloon and the final balloon after secondary blowing of the primary blown balloon.

Fig. 9 is a schematic elevational view of an assembly for the secondary blowing and heat treatment of the primary blown balloon prior to the expansion of the balloon.

Fig. 10 is an enlarged elevational view, partially in section, of the mold and balloon after the secondary blowing of the balloon.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 depicts a tubular member 10 and a preform 11 which is formed out of the tubular member. A holding assembly 12 for transforming the tubular member 10 formed of high strength polymer

material such as PET into a preform 11 is illustrated in Figs 2 and 3. The tubular member 10 is held in a vertical position by the assembly 12 while it is heated by infrared (IR) radiation from long wave IR emitters 13 disposed about the vertically oriented tubular member. The ends 14 and 15 of the tubular member 10 are secured within the assembly 12 by tubing clamps 16 and 17 respectively which are in turn secured to stepping motors 18 and 19 through arms 20 and 21. The extremities of the tubular member 10 are covered by shields 22 and 23 and the center portion 24 of the tubular member which forms the balloon is covered by the shield 25 which is much shorter than the shields 22 and 23. The center portion 24 of the tubular member 10 is secured by the preform clamp 26. As shown in Fig. 2, the shield 25 is held in place by the support for the preform clamp 26.

In operation, the IR emitters 13 direct long wave (about 5 to about 10 microns) infrared radiation at the tubular member 10 but the shields 22-23 and 25 block the application of the IR radiation to the central portion 24 and the extremities of the tubular member so that only the exposed portions 27 and 28 of the tubular member receive the radiation and are heated. The arms 20 and 21, to which the extremities of the tubular member 10 are secured, are moved away from each other by movement of the stepping motors 18 and 19 in the direction of arrows 29 and 30 respectively as shown in Fig. 2. which applies tension to the preform and results in a lengthening of the irradiated portions of the

tubular member 10 and a reduction in the outer diameter thereof. The ends of the tubular center shield 24 have a shadow effect on the exposed portions 27 and 28 of the tubular member 10 immediately adjacent to the center portion 24 shielded by the center shield 26 so as to form the tapers 31 and 32 shown in Fig. 1. The center shielded portion 24 of the tubular member 10 remains essentially unchanged as to size and ultimately forms the cylindrical portion 33 of the preform 11. The final preform product 11 formed by this method is shown in Fig. 1. The distal extremities of the tubular member 10 shielded by shields 22 and 23 are severed after the extension thereof to form the preform 11.

Fig. 4 illustrates the preform 11 and primary blown balloon 34 which is formed from the preform by the assembly 35 shown in Figs. 5 and 6. The assembly 35 includes a water cooled two piece balloon mold 36 with an upper half 37 and a lower half 38. The mold halves 37 and 38, which may be formed of aluminum or other suitable materials, are secured to arms 39 and 40 which, upon movement toward and away from each other, close and open the two piece balloon mold 36. A plurality of short wave length, e.g. about 1 to about 5 microns, IR bulbs 41 are disposed about mold 36 and a plurality of arcuate reflector segments 42 encircle the IR sources as shown in Figs. 6 to concentrate the IR radiation on the central cylindrical portion 33 of the preform 11.

When the temperature of the cylindrical portion 33 of the preform 11 reaches a desired temperature within the visco-elastic region

of the plastic material from which the preform is made (e.g. about 90° to about 110°C.) the water cooled mold halves 37 and 38 are quickly brought together, i.e. closed, and inflation fluid at a pressure of about 100 to about 700 psi is directed to the interior of the preform 11 to expand the center portion 33 and the tapered portions 31 and 32 to the general shape of the interior of the mold 36. As the preform 11 is expanded by the inflation fluid, arms 43 and 44 are moved away from each other as shown by arrows 45 and 46 to apply tension to the preform and stretch the expanded portion so as to generate a very high level of biaxial orientation in the primary blown balloon 34. The arms 43 and 44 are moved apart, as shown in phantom in Fig. 5, by stepping motors (not shown) in essentially the same manner as in the assembly shown in Fig. 2 for making the preform. As shown in more detail in Fig. 7, the primary blown balloon 34 usually does not replicate the exact shape of the interior of the mold 36. The primary blown balloon is shown in Fig. 8 as being very cloudy or opaque. The hoop strength of the balloon at this point is quite high and for PET is about 50 to about 75 ksi and the radial expansion of the primary blown balloon 34 is about 0.0005 inch/atmosphere to about 0.003 inch/atmosphere at a pressure of about 10 atmospheres. The translucent primary blown balloon 34 is highly biaxially oriented due to the extent of the radial expansion and axial elongation the polymer material experiences during the primary blowing.

However, the primary blown balloon 34 may be formed into a clear, high strength balloon 60 with a well defined shape by the method and assembly shown in Figs. 9 and 10. As shown in Fig 9, the primary balloon 34 is placed within the interior of secondary balloon mold 50 which is slightly larger, e.g. about 2 to about 8% larger, preferably about 3 to about 5% larger, than the inflated size of the primary balloon 34. The ends of the primary balloon 34 are secured to arms 51 and 52 which are in turn secured to weights or other suitable tensioning means (not shown) and when the arms are moved in the direction of arrows 53 and 54 tension is applied to the primary balloon at a level of about 5 to about 500 grams, preferably about 300 grams. Inflation fluid at a pressure of about 100 to about 200 psi, typically about 150 psi, is directed, preferably simultaneously with the longitudinal extension, to the interior of the primary balloon 34 while it is at an elevated temperature of about 300° to about 350° F., preferably about 330° to expand the balloon in essentially all directions to remove the "pearlescence" or cloudiness characteristic of the primary blown balloon 34 and to provide the balloon with a highly defined final shape. The secondary balloon mold 50 is a three piece mold with sections 55, 56 and 57 and has heated platens 58 and 59 to heat the primary balloon 34 to the desired temperature for expansion and removal of the cloudiness. The secondary blown balloon 60, as shown in Fig. 10, fills the mold 50 completely and accurately replicates the shaping surfaces of the mold. The final balloon 60 has a

well defined shape, a high degree of clarity and a high tensile strength.

The tubular member 10 is preferably an extruded tube of poly(ethylene) terephthalate which is, for the most part, amorphous in nature. The intrinsic viscosity of the polymer used to form the tube is about 0.8 to about 1.25. During extruding the intrinsic viscosity is reduced and upon primary blowing the intrinsic viscosity of the balloon material is further reduced. After the secondary blowing, the intrinsic viscosity drops even further.

The balloon of the invention may be of conventional size for coronary and peripheral angioplasty such as having a length of about 0.5 to about 20 cm and a maximum inflated diameter of about 0.5 to about 10 mm. While the balloon of the invention may be used in essentially all dilatation catheters for angioplasty procedures, a typical balloon dilatation catheter in which the balloons of the present invention may be used is shown in U.S. Patent No. 5,154,725 (Leopold) which is incorporated herein in its entirely. Other intravascular uses may require different dimensions and shapes other than the cylindrical shape with tapered ends than that described in the presently preferred embodiment described herein. Moreover, while the invention has been described in terms of a PET as the polymer material, the balloon may be made from a wide variety of thermoplastic polymers such as polyesters, polyolefins, polyurethanes and the like. Various other modifications may be made to the present invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. A method of making a high strength polymeric balloon comprising:

a) providing a tubular preform of thermoplastic polymer material;

b) heating the preform to a temperature within the visco-elastic region of the polymer material in those areas thereof which to form a balloon;

c) stretching the heated tubular preform in an axial direction and expanding the heated tubular preform in a radial direction into a first stretched and expanded condition; and

d) heating the preform in the first stretched and expanded condition at a temperature of at least 300° F. for about 0.25 to about 5 minutes and then radially expanding and axially stretching the preform to a second stretched and expanded condition which is larger than the first condition.

2. The method of claim 1 wherein the tubular preform is heated by radiation which passes through the wall of the tubular preform.

3. The method of claim 1 wherein the balloon within is subjected to axial tension between about 5 to about 500 grams.

4. The method of claim 1 wherein the preform is expanded and stretched to the second condition in a second mold which is configured to allow about 2 to about 8% expansion and lengthening when the preform is expanded therein.

5. The method of claim 1 wherein the second mold is configured to allow about 2 to about 5% stretch when the preform is expanded therein.

6. A method of making high strength polymeric dilatation balloons comprising:

a) providing a tubular preform of melt processable thermoplastic polymer material having a cylindrically shaped wall defining an inner lumen therein;

b) passing radiation through the wall of the tubular preform which is to form a balloon to heat the area to a temperature within the visco-elastic region of the polymer material;

c) expanding the heated area of the tubular preform within a first mold by means of fluid at high pressure within the inner lumen thereof.

7. A method of treating a relatively inelastic polymeric blown balloon having a high degree of biaxial orientation to provide clarity and dimensional stability thereto comprising:

a) disposing the relatively inelastic polymeric blown balloon within a mold having an interior of the desire shape and internal dimensions which allow expansion of the blown balloon of at least 1% in all directions;

b) heating the balloon to a temperature between about 140° and about 160° C.; and

c) inflating the heated balloon to a pressure above about 50 psi to cause the balloon to take the shape of the interior of the mold.

8. The method of claim 7 wherein the balloon is subjected to tension while inflated at about 5 to about 500 gram-force.

9. A high molecular weight inelastic polymeric balloon which is clear, which is highly biaxially oriented, which has a hoop strength of at least 50 ksi.

10. A clear high molecular weight inelastic polymeric balloon having

a) a cylindrically shaped working section which is highly oriented in two directions, which has a tensile strength of at least 50 ksi in the hoop direction;

b) proximal and distal tapered sections on proximal and distal ends of the working section which have diameters decreasing in the direction away from the working section; and

c) proximal and distal skirts.

11. The balloon of claim 10 formed of a poly(ethylene) terephthalate.

12. A method of preparing a polymeric preform from a polymeric tubular member for expansion into a dilatation balloon which has a cylindrical working portion and end portions which taper away from the working portion to smaller diameters comprising:

a) shielding a part of the polymeric tubular member which is to be expanded into the working portion of the balloon;

b) radiation heating the tubular member on both sides immediately adjacent the shielded part; and

c) applying tension to the tubular member so as to extend longitudinally and thereby reduce the outer diameter of the radiation heated portions of the tubular member.

13. The method of claim 12 wherein the extended tubular member is cooled to a temperature which prevents crystallization of the material from which the preform is made.

FIG. 1

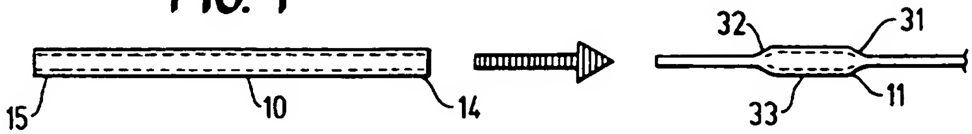

FIG. 2

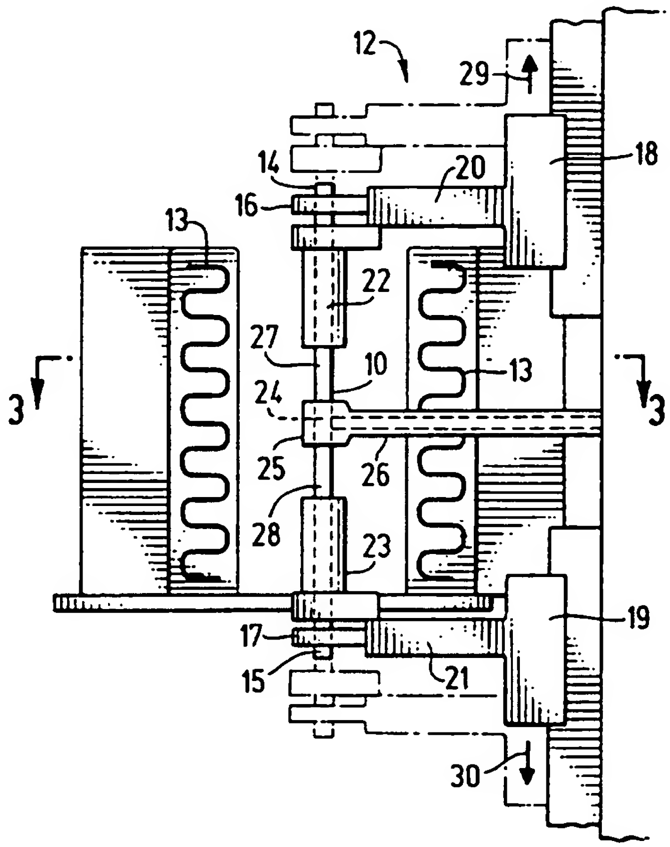

FIG. 3